UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

JUL 17 2013

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REPLY TO THE ATTENTION OF:

Robert W. MacKay
Vice President Operations
General Manager
Amylin Ohio, L.L.C.
8814 Trade Port Drive
Hamilton, Ohio 45011

Dear Mr. MacKay:

Enclosed is an executed original of the final Administrative Consent Order (ACO) which addresses the self-disclosed violations in your November 20, 2012 audit agreement request letter sent to the U.S. Environmental Protection Agency. The ACO requires Brisol-Myer Squibb Company and Amylin Ohio, L.L.C. (jointly, BMS) to install three cryogenic condensers at the Hamilton facility's two process lines and all the tanks at the tank farm. The cryogenic condensers will achieve 98% reduction of hazardous air pollutants from these emission sources. In addition, the ACO establishes a compliance schedule for the Hamilton facility to implement the National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Productions.

Please direct any questions regarding this case to Kris Vezner, Associate Regional Counsel at (312) 886-6827.

Sincerely,

Brian Dickens
Section Chief, AECAS (MN/OH)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**EPA-5-13-113(a)-OH-2**
	)	
Bristol-Myers Squibb Company	)	**Proceeding Under Sections 113(a)(1)(3) and**
and Amylin Ohio LLC	)	**114(a)(1) of the Clean Air Act, 42 U.S.C.**
Hamilton, Ohio	)	**§§ 113(a)(1)(3) and 114(a)(1)**

Administrative Consent Order

1. The Director of the Air and Radiation Division, U.S. Environmental Protection Agency (EPA), Region 5, is issuing this Administrative Consent Order (Order) to Bristol-Myers Squibb Company and Amylin Ohio LLC (collectively, BMS) under Sections 113(a)(1)(3) and 114(a)(1) of the Clean Air Act (CAA), 42 U.S.C. §§ 7413(a)(1)(3) and 7414(a)(1).

Statutory and Regulatory Background

2. Under Section 112 of the CAA, 42 U.S.C. § 7412, EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production, at 40 C.F.R. Part 63, Subpart GGG (Subpart GGG).

3. Subpart GGG generally applies to the owner or operator of a "pharmaceutical manufacturing operation" (as defined at 40 C.F.R. § 63.1251) that meets all three of the following criteria: it 1) manufactures a "pharmaceutical product" (as defined at 40 C.F.R. § 63.1251); 2) is located at a plant that is a "major source" (as defined in Section 112 of the CAA, 42 U.S.C. § 7412); and 3) processes, uses or produces hazardous air pollutants (HAPs). See 40 C.F.R. § 63.1250(a).

4. Subpart GGG requires an affected source to control HAP emissions from its pharmaceutical manufacturing operations.

5. Under Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3), the Administrator of EPA may issue an order requiring compliance to any person who has violated or is violating the NESHAP regulations. The Administrator has delegated this authority to the Director of the Air and Radiation Division.

6. Under Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1), the Administrator of EPA may require any person who owns or operates an emission source to make reports and provide information required by the Administrator. The Administrator has delegated this authority to the Director of the Air and Radiation Division.

Findings

7. Bristol-Myers Squibb Company owns and operates a pharmaceutical production facility at 8814 Trade Port Drive, Hamilton, Ohio (BMS facility). Bristol-Myers Squibb Company has stated that it owns and operates the BMS facility through its affiliates, as Amylin Ohio LLC.

8. The BMS facility includes a facility-wide collection of pharmaceutical manufacturing process units (PMPUs, as defined at 40 C.F.R. §63.1251) and any other equipment such as heat exchanger systems, wastewater and waste management units, or cooling towers that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

9. The BMS facility is a "pharmaceutical manufacturing operation", as defined at 40 C.F.R. § 63.1251.

10. At the BMS facility, BMS manufactures a "pharmaceutical product" as defined at §63.1251.

11. The BMS facility is located at a plant that is a "major source" as defined in Section 112 of the CAA, 42 U.S.C. § 7412.

12. At the BMS facility, BMS processes, uses or produces HAPs.

13. At the BMS facility, BMS is subject to Subpart GGG.

14. At the BMS facility, BMS owns or operates an "emission source" within the meaning of Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1). Therefore, regarding the BMS facility, BMS is subject to the requirements of Section 114(a)(1).

15. On November 20, 2012, BMS submitted a request to enter into an audit agreement with EPA under the New Owner Voluntary Self-Disclosure Policy.

16. On November 20, 2012, BMS submitted a determination request to EPA regarding potential applicability to the BMS facility of 1) the NESHAP for Chemical Manufacturing Area Sources, at 40 C.F.R. Part 63, Subpart VVVVVV; and 2) Subpart GGG.

17. On January 8, 2013, EPA issued to BMS a response stating that the BMS facility is subject to Subpart GGG.

18. During discussions with EPA regarding this matter, BMS has stated that through its affiliates, it is a new owner of the BMS facility, having acquired the BMS facility on August 8, 2012 from Amylin Pharmaceutical LLC.

19. During discussions with EPA regarding this matter, BMS has been cooperative.

20. During discussions with EPA regarding this matter, BMS has stated that the emission controls that it will install at the BMS facility to comply with Subpart GGG requirements will be more protective than Subpart GGG requires.

21. BMS neither admits nor denies the matters set forth in the Findings.

Compliance Program For the BMS Facility

22. By October 31, 2013, BMS must submit to the Ohio Environmental Protection Agency a complete Title V permit application incorporating Subpart GGG's requirements.

23. By August 31, 2013, BMS must submit to the EPA contact in paragraph 27, below, the design evaluation required by 40 C.F.R. §§ 63.1257(a)(1) and 63.1260(f)(2) for the cryogenic condensers to be installed at each bulk line for its Bydureon manufacturing operations and for all the tanks at BMS facility's tank farm. To demonstrate that the condenser meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control device. Additionally, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design outlet organic HAP compound concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet. The temperature of the gas stream exiting the condenser must be measured and used to establish the outlet organic HAP concentration. If the vent stream is not the only inlet to the control device, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control device. BMS must also submit this document as part of its notification of compliance status, according to the schedule in paragraph 25, below.

24. By February 28, 2014, BMS must install a cryogenic condenser that meets the submitted design evaluation at each bulk line for its Bydureon manufacturing operations and for all the tanks at BMS facility's tank farm that reduces its outlet organic HAP concentration by at least 98 percent.

25. By March 31, 2014, BMS must achieve, demonstrate and maintain compliance with Subpart GGG at the BMS facility. This process must include but is not limited to the following submissions to EPA and/or implementations:

a. Initial notification for Subpart GGG. See 40 C.F.R. §§ 63.9(b)(2), 63.1260(b).

b. Notification of compliance status for Subpart GGG. See 40 C.F.R. §§ 63.9(h), 63.1260(f).

c. Developing and implementing a leak detection and repair program for all pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, agitators, connectors, control devices, instrumentation systems, and closed-vent systems subject to Subpart GGG. See 40 C.F.R. § 63.1255.

26. Under Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1), BMS must provide records, reports and information (collectively, "documents") as follows: provide the documents described in paragraph 23, above to the EPA contact in paragraph 27, below, by the submission date in paragraph 23; and 2) provide the documents described in paragraphs 25.a and 25.b, above, to the EPA contact in paragraph 27, below, by March 31, 2014.

27. BMS must send all documents required by paragraphs 23 and 26, above, and all communications regarding this Order, to:

Attention: Compliance Tracker (AE-17J)
Air Enforcement and Compliance Assurance Branch
U.S. Environmental Protection Agency, Region 5
77 W. Jackson Boulevard
Chicago, Illinois 60604
(312) 886-0120

General Provisions

28. This Order does not affect BMS's responsibility to comply with other federal, state and local laws. These responsibilities include but are not limited to BMS's obligations

under Subpart GGG and other CAA regulations to submit the documents referenced in paragraphs 23 and 25, above, to other offices or persons at EPA than the EPA contact at paragraph 27, above.

29. This Order does not restrict EPA's authority to enforce Section 112 of the CAA or any other section of the CAA.

30. Nothing in this Order limits the EPA's authority to seek appropriate relief, including penalties, under Section 113 of the CAA, 42 U.S.C. § 7413, for BMS's violations of Subpart GGG.

31. Failure to comply with this Order may subject BMS to penalties of up to $37,500 per day for each violation under Section 113 of the CAA, 42 U.S.C. § 7413, and 40 C.F.R. Part 19.

32. The terms of this Order are binding on BMS, its assignees and successors. BMS must give notice of this Order to any successors in interest prior to transferring ownership and must simultaneously verify to EPA, at the above address, that it has given the notice.

33. BMS may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B, for any portion of the information it submits to EPA. Information subject to a business confidentiality claim is available to the public only to the extent allowed by 40 C.F.R. Part 2, Subpart B. If BMS fails to assert a business confidentiality claim, EPA may make all submitted information available, without further notice, to any member of the public who requests it. Emission data provided under Section 114 of the CAA, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2, Subpart B. "Emission data" is defined at 40 C.F.R. § 2.301.

34. This order is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, because it seeks collection of information by an agency from specific individuals or entities as part of an administrative action or investigation. To aid in our electronic recordkeeping efforts, please furnish an electronic copy on physical media such as compact disk, flash drive or other similar item. If it is not possible to submit the information electronically, submit the response to this Order without staples; paper clips and binder clips, however, are acceptable.

35. EPA may use any information submitted under this Order in an administrative, civil judicial or criminal action.

36. BMS agrees to the terms of this Order.

37. This Order is effective on the date of signature by the Director of the Air and Radiation Division. This Order will terminate two years from the effective date, provided that BMS has complied with all terms of the Order throughout its duration.

38. "Force majeure," for purposes of this Order, is defined as any event arising from causes beyond the control of BMS, of any entity controlled by BMS or of BMS's contractors that delays or prevents the performance of any obligation under this Order despite BMS's best efforts to fulfill the obligation. The requirement that BMS exercise "best efforts to fulfill the obligation" includes using best efforts to anticipate any potential force majeure and best efforts to address the effects of any potential force majeure (a) as it is occurring and (b) following the potential force majeure such that the delay and any adverse effects of the delay are minimized to the greatest extent possible. "Force majeure" does not include financial inability to complete the work, or a failure to comply with Subpart GGG or any other federal, state and local law.

39. If any event occurs or has occurred that may delay the performance of any obligation under this Order for which BMS intends or may intend to assert a claim of force

majeure, BMS shall notify EPA's contact point at paragraph 27, above, orally or, in his or her absence, the Director of the Air and Radiation Division, EPA Region 5, within 48 hours of when BMS first knew that the event might cause a delay. Within 3 business days thereafter, BMS shall provide in writing to EPA an explanation and description of the reasons for the delay; the anticipated duration of the delay; all actions taken or to be taken to prevent or minimize the delay; a schedule for implementation of any measures to be taken to prevent or mitigate the delay or the effect of the delay; BMS's rationale for attributing such delay to a force majeure; and a statement as to whether, in the opinion of BMS, such event may cause or contribute to an endangerment to public health or welfare, or the environment. BMS shall include with any notice all available documentation supporting its claim that the delay was attributable to a force majeure. BMS shall be deemed to know of any circumstance of which BMS, any entity controlled by BMS, or BMS's contractors knew or should have known. Failure to comply with the above requirements regarding an event shall preclude BMS from asserting any claim of force majeure regarding that event, provided, however, that if EPA, despite the late notice, is able to assess to its satisfaction whether the event is a force majeure under Paragraph 38, above, and whether BMS has exercised its best efforts under Paragraph 38, EPA may, in its unreviewable discretion, excuse in writing BMS's failure to submit timely notices under this paragraph.

40. If EPA agrees that the delay or anticipated delay is attributable to a force majeure, the time for performance of the obligations under this Order that are affected by the force majeure will be extended by EPA for such time as is necessary to complete those obligations. An extension of the time for performance of the obligations affected by the force majeure shall not, of itself, extend the time for performance of any other obligation. If EPA does not agree that the delay or anticipated delay has been or will be caused by a force majeure, EPA will notify

Settling Defendants in writing of its decision. If EPA agrees that the delay is attributable to a force majeure, EPA will notify BMS in writing of the length of the extension, if any, for performance of the obligations affected by the force majeure.

6/28/13
Date

Katherine Kelly
Vice President and Assistant General Counsel
Bristol-Myers Squibb Company

28 JUNE 2013
Date

Robert W. MacKay
Vice President Operations
General Manager
Amylin Ohio LLC

7/17/13

Date

George T. Czerniak
Director
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5